

Appn. No. 10/065,595
Docket No. 125974/GEM-0053

REMARKS / ARGUMENTS

Status of Claims

Claims 1-13, 16-18, 20-28, 30 and 34-42 are pending in the application and stand rejected.

The Examiner has rejected claims 1-13, 16-18, 20-28, 30, 34-37, 40 and 42 under 35 U.S.C. §112, first paragraph.

The Examiner has objected to claims 1-13, 16-18, 20-28, 30, 34-37, 40-42 due to informalities.

The Examiner has rejected claims 1-6, 9-13, 16-18, 20-28, 30, 37 and 40 under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan et al., Chen et al., Ockuly and Farsaie or Migdal et al.

The Examiner has rejected claims 7, 8, 34-36 under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan et al., Chen et al., Ockuly and Farsaie or Migdal et al and further in view of Liu et al.

The Examiner has rejected claim 42 under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan et al., Chen et al., Ockuly and Farsaie or Migdal et al and further in view of Pan et al.

The Examiner has rejected claims 38, 41 under 35 U.S.C. §103(a) as being unpatentable over Liu et al. in view of Langberg et al. or Foltz et al.

Further, the Examiner has rejected claim 39 under 35 U.S.C. §103(a) as being unpatentable over Liu et al. in view of Langberg et al. or Foltz et al., and further in view of Subramanyan et al., or Chen et al.

Applicant has amended claims 1, 16, 40 and 42 for consideration upon entry of the present Amendment, with Claims 40 and 42 being amended herein to address typographical errors. Claims 43-49 are newly added claims. Applicant respectfully submits that the amendment submitted herein addresses the objections and rejections of the Examiner and that no new matter has been entered.

Appln. No. 10/065,595
Docket No. 125974/GEM-0053

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-13, 16-18, 20-28, 30, 34-37, 40, 42 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Examiner comments that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art, at the time the application was filed, that the Applicant had possession of the claimed invention.

Applicant respectfully disagrees with the Examiner's rejection for at least the following reasons.

Referring to the application as originally filed, Claim 29 claimed, in part, "exporting a 3D model in at least one" where the one made reference to the various formats. Also referring to the letter from Applicant dated October 3, 2005, page 13, the limitations of Claim 29 were included in Claims 1 and 16, which have now been amended to incorporate the limitations into Claims 48 and 49.

MPEP §608.01(l) establishes, among other things, that applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it. Where subject matter not described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits. The claim should not be attacked either by objection or rejection.

Accordingly, in various places, the description is amended herein to include the phrase "at least one" as claimed in original Claim 29 (and included in Claims 1 and 16). No new matter has been added.

Further, it is pointed out that the specification (page 17) states that "the invention will include all embodiments falling within the scope of the appended claims." It is therefore considered that Claim 29, as originally submitted, is within the teachings of the application at the time the application was filed.

It is respectfully submitted that the specification as originally filed, and as now amended, reasonably conveys that the Applicant had possession of the claimed invention,

Appl. No. 10/065,595
Docket No. 125974/GEM-0053

and that Claims 1-13, 16-18, 20-28, 30, 34-37, 40 and 42 are therefore patentable, as well as newly added Claims 48 and 49. The Applicant requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Claim Objections

The Examiner has objected to claims 1-13, 16-18, 20-28, 30, 34-37, 40-42. Claims 1 and 16 have been objected to as being allegedly unclear as to what structure/steps applicant is referring to; and, the phrase "each image slice" lacks antecedent basis. Claim 41 has been objected to as an unclear limitation of the base claim.

Claims 1 and 16 have been amended and incorporate clarifications that address the objections of the Examiner.

Regarding objection to Claim 41, nowhere in the base claim, Claim 38, is "acquiring" recited. As Claim 41 recites "acquiring the cardiac image data" it is respectfully submitted that Claim 41 is a clear limitation to the base claim.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this objection.

Rejections Under 35 U.S.C. §103(a)

Claims 1-6, 9-13, 16-18, 20-28, 30, 37, 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan et al., Chen et al. (WO 96/10949 hereinafter Chen) Ockuly and Farsaie or Migdal et al.

Regarding Independent Claim 1

Applicant has amended Claim 1 to now recite, inter alia,

***"...an image generation system configured for generating at least one viewable image from the volume of cardiac image data through dynamic segmentation;
a database configured for storing information from said data acquisition and image generation systems, and for storing a 3D model of at least the dynamically segmented volume of cardiac image data;***

Apph. No. 10/065,595
Docket No. 125974/GBM-0033

an operator interface system configured for managing at least one of said medical scanner system, said data acquisition system, said image generation system, and said database;

a post-processing system configured for analyzing the volume of cardiac image data, inserting at least three geometric markers into the volume of cardiac image data at corresponding anatomical landmarks, selecting a viewable parameter in response to the geometric marker at the anatomical landmark, generating the 3D model of the volume of cardiac image data, displaying the at least one viewable image, exporting the 3D model with the at least three geometric markers to said operator interface system, and being responsive to said operator interface system; and wherein...

thereby providing an imaging system for use in interventional procedure planning that makes available, prior to an actual medical interventional procedure, the 3D model with the at least three geometric markers for subsequent registration with an interventional system for use during a subsequent interventional procedure."

Dependent claims inherit all of the limitations of the parent claim. No new matter has been added as a discussion of dynamic segmentation, geometric markers, anatomical landmarks, and interventional procedure planning, is provided in the specification in various places, such as at Paragraphs [0024] and [0035] for example. Furthermore, in paragraph [0022] the specification teaches:

"The post-processing software used in post-processing system 180 performs segmentation of cardiac image volume data to extract relevant substructures such as the right atrium and coronary sinus vessel, defining a subvolume or 3D model of the substructure.

It is also noteworthy that the specification separately discusses analytical methods for performing vessel tracking. Refer at least to paragraph [0023].

The Examiner has asserted that Keidar et al. discloses a system "including everything" (in Claim 1) "except for a database, an operator interface and a post-processing system." Paper 20051209, page 3.

Appln. No. 10/065,593
Docket No. 125974/GEM-0053

Applicant submits that Keidar does not disclose, teach or suggest "dynamic segmentation" as is claimed in Claim 1. Applicant further submits that Keidar does not disclose, teach or suggest "interventional procedure planning" as is claimed in Claim 1.

Keider teaches a process where, "when higher resolution is required, the registration of the diagnostic image with the geometrical map may be improved using methods,... described in Appendix A" (col. 7, lines 7-11). Appendix A provides details in which two 3D representations are "brought into mutual registration" (col. 8, lines 28-29). Keider does not disclose, teach or suggest "generating at least one viewable image from the volume of cardiac image data *through dynamic segmentation*", as is claimed in Claim 1.

Keider also teaches a process of "generating a 3D geometrical map of the structure using a probe inserted into the structure" (col. 2, lines 50-51), and "sensors used in catheter 20" (col. 5, lines 17-18). Keider does not disclose, teach or suggest ***"providing an imaging system for use in interventional procedure planning that makes available, prior to an actual medical interventional procedure, the 3D model with the at least three geometric markers for subsequent registration with an interventional system for use during a subsequent interventional procedure"***, as is claimed in Claim 1.

Further, Applicant submits that none of the other references cited by the Examiner disclose, teach or suggest "dynamic segmentation", or ***"an imaging system for use in interventional procedure planning that makes available, prior to an actual medical interventional procedure, the 3D model with the at least three geometric markers for subsequent registration with an interventional system for use during a subsequent interventional procedure"***, as is claimed in Claim 1.

For example, Subramanyan et al. discloses that "a vessel direction is estimated." Subramanyan et al. discloses four methods: a first involves "fitting the points"; while in a second, "the centerline is tracked"; a third involves a method "to weight the points"; and, a fourth involves "line filtering a finite volume" (col. 4, lines 31-50). "To improve the boundaries' detectability, and edge enhancement 80 is optionally performed." In one embodiment, edge enhancement includes "a Gaussian function convolutional smoothing."

Appl. No. 10/065,595
Docket No. 125974/GEM-0053

(col. 5, lines 6-9). Subramanyan et al. does not disclose, teach or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

Chen et al. discusses "proper registration" and superimposing (page 23) but does not disclose or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

Ockuly does not disclose or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

Regarding Farsaie and Migdal et al., Appellant objects to the use of these patents, for at least the following reasons. First, it is considered that Farsaie and Migdal et al., are not analogous art. These patents are not in the field of the present application. Further, these patents are not reasonably pertinent to "an imaging system for use in medical intervention procedure planning" as is claimed in Claim 1.

Further, and in regard to Farsaie, it is considered that this patent may not be properly available as prior art. That is, when determining the effective date of filing of a prior art reference, if the application properly claims benefit to a provisional application, the effective filing date is the filing date of the provisional application for any *claims* that are *fully supported* by the provisional application.

As Farsaie was filed *after* the present application, use of Farsaie as a reference relies upon the presumption that the subject matter therein is fully supported by the referenced provisional application. There is no evidence that the subject matter relied upon by the Examiner is disclosed in the provisional application, and the Applicant does not agree to this presumption. Therefore, Applicant specifically objects to the use of Farsaie as a prior art reference.

However, and only for the sake of argument, and should the Examiner consider Farsaie and Migdal et al. to be proper references, it is respectfully submitted that neither Farsaie nor Migdal et al. disclose, teach or suggest "dynamic segmentation" or

Appl. No. 10/065,595
Docket No. 125974/OEM-0053

"interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

More specifically, Farsaie calls for, among other things, "applying known transformations" or "applying unknown transformations." 3d-spels are generated. (paragraph [0076]). "After the 3d-spels are calculated, they are merged into a single data set. This allows a point cloud generation of the entire space or object." (paragraph [0158]). A mesh is built from the 3d-spels. (paragraph [0168]). Farsaie does not disclose, teach or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

Migdal, et al., call for a plurality of data points and a texture map file, which the computer system therein uses to build a series of meshes. (col. 12, lines 27-31). Although a number of techniques are disclosed in Migdal et al., the teachings do not disclose, teach or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 1.

It is considered that for at least the foregoing reasons that Claim 1, and Claims 2-13, 40, 43 and 44 dependent thereon, are patentable over the prior art of record. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims.

Regarding Independent Claim 16

Applicant has amended Claim 16 to include limitations similar to those of amended Claim 1.

The distinctions over the prior art submitted herein in regard to Claim 1, and claims dependent thereon, are also applicable to Claim 16. That is, the prior art of record does not disclose or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claim 16, and the claims dependent thereon.

App'n. No. 10/065,595
Docket No. 125974/GEM-0053

Further, the objections submitted regarding the use of Farsaie and Migdal et al., are also submitted in regard to rejection of Claim 16, and the claims dependent thereon.

Accordingly, it is considered that for at least the foregoing reasons that Claim 16, and Claims 17, 18, 20-28, 30, 34-37 and 45-48 dependent thereon, are patentable over the prior art of record. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims.

Regarding Claims 7, 8, 34-36

Examiner has rejected claims 7, 8, 34-36 under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan et al., Chen et al., Ockuly and Farsaie or Migdal et al and further in view of Liu et al.

It is considered that claims 7, 8 and 34-36 are patentable over the prior art of record for at least the reasons presented with respect to the independent Claims 1 and 16.

In regard to Lui, et al., Applicant submits that Lui et al. does not disclose, teach or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed in Claims 1, 7, 8, 16 and 34-35.

Rather, Lui et al discloses *estimation* of the 3-D arterial or venous tree "by vessel segmentation and separation." (paragraph [0075]). A preferred embodiment is disclosed where "*seeds* corresponding to the starting locations 86, 88 are grown." Edge preservation preferably involves "3-D morphological smoothing and isotropic volume generation." (paragraph [0076]).

The Examiner has asserted that Lui et al. discloses segmentation using any known post-processing technique, and has further asserted that in the absence of criticality or unexpected result, the technique (presumed to be Applicant's technique) would have been an obvious design choice.

In this regard, it is first noted that Lui et al only discloses **segmentation and separation**, performed in a preferred embodiment. As there are no other "known post-processing technique(s)" in the record, it is improper to assume that Lui et al. encompasses *all* segmentation and separation techniques including "dynamic

Appn. No. 10/065,595
Docket No. 125974/GEM-0053

segmentation" as claimed in the instant invention. It is considered that Lui et al. does not disclose, teach or suggest "dynamic segmentation" or "interventional procedure planning" employing a "3D model with... at least three geometric markers for subsequent registration" as is claimed by Applicant.

As stated in the specification, in "contrast-enhanced segmentation analysis" in post-processing "Image brightness is established prior to segmentation and in accordance with the presence of an arterial or venous-phase study." "Since the intensity of the voxels within the coronary sinus would be lower for images from an arterial phase data acquisition, due to the influence that blood has on the image intensity, the segmentation threshold value must be adjusted appropriately in order to obtain correct segmentation imaging." The algorithm for automatically adjusting the dynamic segmentation threshold value provides the post-processing software with a capability to automatically distinguish between the different image contrasts.

In view of the foregoing, Applicant submits that Liu et al. does not disclose, teach or suggest any of the foregoing techniques, and specifically does not disclose, teach or suggest "dynamic segmentation" as is claimed by Applicant.

Regarding Claims 38 and 41

Claim 38 recites, inter alia,

"...dynamically adjusting a segmentation threshold in preparation for performing vessel tracking of the coronary sinus from the volume of cardiac image data, thereby enabling the coronary sinus to be tracked for both arterial-phase and venous-phase contrast enhanced studies."

Claim 41 depends from Claim 38 and therefore inherits all of the limitations of the parent claim.

In alleging obviousness of Claim 38, Applicant submits that the Examiner has not shown with specificity where the references teach or suggest the claimed limitation of "dynamically adjusting a segmentation threshold...". Absent a showing of each and every element arranged so as to perform as the claimed invention performs, a prima facie

App'n. No. 10/063,595
Docket No. 125974/GEM-0033

case of obviousness cannot properly be established. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Regarding Claim 39

Claim 39 depends from Claim 38, and for at least the reasons set forth above regarding the allowability of Claim 38, Applicant submits that Claim 39 is also allowable. Furthermore, Applicant respectfully submits that the additional references applied against Claim 39 fail to cure the deficiencies of those applied against Claim 38.

Further, it is noted that Applicant submitted certain arguments on August 8, 2005 to which the Examiner has not fully responded. As a complete response to arguments was not provided by the Examiner, Applicant herein reiterates the arguments submitted on August 8, 2005. More specifically, in Applicant's arguments of August 8, 2005, Applicant respectfully submitted that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also **suggests the desirability of the combination**. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (emphasis added). "[T]o establish obviousness based on a combination of the elements disclosed in the prior art, there must be **some motivation, suggestion or teaching of the desirability** of making the specific combination that was made by the applicant." *In re Werner Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (citing: *In re Dance*, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (emphasis added). **There must also be a reasonable expectation of success in modifying or combining the prior art**, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 USPQ2d 1016, 1023 (Fed. Cir. 1996) (Emphasis added). And, **there must be some degree of predictability in showing the reasonable expectation of success**. *In re Rinehart*, 189 USPQ 143 (CCPA 1976); MPEP §2143.03 (Emphasis added).

AppIn. No. 10/065,595
Docket No. 125974/GEM-0053

With regard thereto, Applicant argued that the prior art of record lacked a proper showing of a *prima facie* case of obviousness. Applicant respectfully incorporates herein the same arguments in this instant response. More specifically, Applicant finds no motivation *in the prior art references themselves* to modify Keidar (disclosing an interventional procedure employing a catheter with sensors to generate a surface map of the heart) by using Subramanyan (disclosing estimation of vessel direction through an extrapolation technique for stent replacement), and Chen (disclosing video imaging with proper registration and superimposing of a virtual image), and Ockuly (disclosing an interventional procedure involving a steerable catheter), and Parsaie and Migal (applied for their disclosure of a wire mesh model).

In comparing the seemingly disjointed combination of subject matter disclosed in the prior art of record, which includes *interventional* procedures, *non-interventional* procedures, *video* imaging, *CT* imaging, *estimated* vessel tracking, and *sensorized catheter* tracking, to the claimed invention, Applicant is at a loss to see how one skilled in the art would be motivated to combine the references as suggested by the Examiner to arrive at the claimed invention.

Combining prior art directed to *an interventional procedure* with other prior art is entirely contrary to the purpose of the claimed invention, which provides an imaging system for use in interventional procedure *planning* that makes available, *prior to* an actual medical interventional procedure, the 3D model with the at least three geometric markers *for subsequent registration* with an interventional system for use during *a subsequent interventional procedure*. Modification of the primary reference to Keidar (disclosing *an interventional procedure* employing a catheter with sensors to generate a surface map of the heart) results in a combination that has an entirely different purpose to that of the claimed invention.

Should the Examiner remain unconvinced of the patentability of the pending claims, Applicant respectfully requests a response on the merits to all arguments previously presented, including the aforementioned argument directed to a lack of

Appl. No. 10/065,595
Docket No. 125974/GEM-0053

motivation in the prior art references themselves to combine the references to arrive at the claimed invention.

Additional Claims

Claims 43-49 are newly added herein. These claims are dependent from one of Claim 1 and Claim 16, and further claim subject matter related to dynamic segmentation as disclosed in the specification. No new matter has been added.

Conclusion

For at least the foregoing reasons, it is believed that all pending and newly added claims are novel and patentable over the prior art of record. Further, it is considered that the foregoing amendments and remarks fully comply with and are responsive to the Office Action and that the claims herein should now be allowable to Applicant. Accordingly, reconsideration and allowance is requested. It is submitted that the foregoing amendments and remarks should render the case in condition for allowance.

Appl. No. 10/065,595
Docket No. 125974/GRM-0093

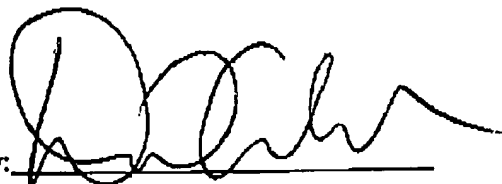
The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 07-0845.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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